K130962

R & D Systems, Inc.
R&D 5D Retic Hematology Control

June 26, 2013

# 510(k) Summary

JUL 2 4 2013

## Submitter Information

R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
Contact: Ambreen Athar
Phone: 612-379-2956 (ext. 4136)
Fax: 612-379-6580
Date Prepared: June 26, 2013

## Device Information

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|---|---|
| Proprietary Name: | R&D 5D Retic Hematology Control |
| Common Name: | Hematology Controls |
| Classification | 21 CFR 864.8625 |
| Classification Name: | Hematology Quality Control Mixture |
| Product Code: | JPK |
| Device Class: | II |
| Panel: | Hematology (81) |

## Unmodified Predicate Device

R&D Systems CBC-5D Plus Retics Hematology Control, (K072096) manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413.

## Description of Device

The R&D 5D Retic Hematology Control is an *in vitro* diagnostic reagent composed of human in a plasma-like fluid with preservatives. It is composed of stabilized materials that provide a means of monitoring reticulocyte counting methods. It is sampled in the same manner as a patient specimen.

## Intended Use:

R&D 5D Retic Control is a tri-level, assayed Hematology control designed to monitor RET%, RET#, IRF and MRV values on Coulter® hematology analyzers.

## Technological Comparison to Predicate

The modified device has the same technological characteristics as the legally marketed predicate device. Both are used to perform quality control assays and both products are used to monitor values obtained from Coulter® hematology analyzers. The predicate device is assayed for WBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, NEUT #, LYMPH #, MONO #, EO #, BASO #, NEUT%, MONO%, LYMPH%, EO%, BASO%, NRBC#, NRBC% , RBC, RET%, RET#, and IRF whereas the R&D 5D Retic Hematology Control is assayed for only RET%, RET#, IRF, and MRV parameters.

## Summary of Performance Data

Laboratory testing of 3 validation lots has shown the R&D 5D Retic Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The R&D 5D Retic Hematology Control passed the acceptance criteria of remaining within range over the life of the product. Expiration dating will be established at 105 days (closed vial) and 14 days (open vial) when stored at 2 - 8° C and handled according to instructions for use.

## Substantial Equivalence Conclusion

The data demonstrate that the R&D 5D Retic Hematology Control is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

R&D SYSTEMS, INC.
c/o MS. AMBREEN ATHAR
QA/RA SPECIALIST
614 MCKINLEY PLACE, N.E.
MINNEAPOLIS MN 55413

Re: K130962
Trade/Device Name: R&D 5D Retic
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: II
Product Code: JPK
Dated: June 26, 2013
Received: July 12, 2013

Dear Ms. Athar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K130962**

Device Name: **R&D 5D Retic Hematology Control**

Indications for Use:

**R&D 5D Retic Control is a tri-level, assayed Hematology control designed to monitor RET%, RET#, IRF and MRV values on Coulter® hematology analyzers.**

**For *in vitro* Diagnostic Use Only.**

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Leonthena R. Carrington -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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